IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ASTRAZENECA AB and
ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs/Counter-Defendants,

v. **CIVIL ACTION NO. 1:18CV193**
(Judge Keeley)

MYLAN PHARMACEUTICALS INC., **c/w 1:19CV203**
3M COMPANY, and
KINDEVA DRUG DELIVERY, L.P.,

Defendants/Counter-Claimants.

MEMORANDUM OPINION AND ORDER ADOPTING ASTRAZENECA'S PROPOSED CONSTRUCTION OF THE TERM "0.001%"

This patent infringement case involves four United States Patents issued to AstraZeneca AB and sold and distributed by AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"). Specifically, the patents at issue are U.S. Patent Nos. 7,759,328 ("the '328 patent"), 8,143,239 ("the '239 patent"), 8,575,137 ("the '137 patent"), and the 10,166,247 ("the '247 patent) (collectively, "the patents-in-suit"). AstraZeneca uses the pharmaceutical compositions and methods described in these patents to produce Symbicort® (budesonide/formoterol fumarate dihydrate), a prescription drug approved for the treatment of asthma in patients 6 years of age and older and maintenance treatment in patients with chronic obstructive pulmonary disease ("COPD"), including bronchitis and emphysema.

Pending before the Court is the parties' proposed competing

ASTRAZENECA AB ET AL. v. MYLAN ET AL. **1:18CV193**
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claim construction of the term "0.001%". The Court adopts AstraZeneca's proposed construction of the term "0.001%" for the reasons that follow.

I. BACKGROUND

According to AstraZeneca, 3M Company, through its 3M Drug Delivery Systems division, submitted Abbreviated New Drug Application ("ANDA") No. 211699 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of budesonide and formoterol fumarate dihydrate inhalation aerosol, 80 mcg/4.5 mcg and 160 mcg/4.5mcg ("Mylan's ANDA Products") (Dkt. No. 285 at 5-6). On August 17, 2018, 3M transferred certain interests in ANDA No. 211699 to Mylan Pharmaceuticals Inc. Id. at 6. Thereafter, in a letter dated August 30, 2018, Mylan notified AstraZeneca that it had filed ANDA No. 211699 seeking approval to market Mylan's ANDA Products prior to the expiration of the patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations for Symbicort. Id. In its letter, Mylan asserted that the '328, '239, and '137 patents are invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. Id.

In a second letter dated October 11, 2019, Mylan notified AstraZeneca that it had submitted a certification to the FDA to

obtain approval to engage in the commercial manufacture, use, or sale of the product described in ANDA No. 211699 prior to the expiration of the '247 patent. Id. at 8. Mylan also asserted in its second letter that the '247 patent was invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. Id. Following receipt of Mylan's letters, AstraZeneca filed this patent infringement suit, which also seeks a declaration of infringement of the patents-in-suit (Dkt. No. 285).

II. LEGAL STANDARDS

The construction of patent claims is a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the context, the specification, and the prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). The description of an

invention in the claims, therefore, limits the scope of the invention. Id. "[T]here is no magic formula or catechism for conducting claim construction." Id. at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." Id.

"[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." Id. at 1321 (internal quotation marks omitted).

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in

question is not present in the independent claim." Id. at 1314-15 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)).

Pursuant to 35 U.S.C. § 112, ¶ 1, an inventor must use the patent specification to describe the claimed invention in "full, clear, concise, and exact terms." The patent specification therefore "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

"[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." Phillips, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Hill-Rom Servs., Inc. v. Stryker Corp., 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting Liebel-Flarsheim, 358 F.3d at 906) (internal quotation marks omitted).

Nevertheless, a court may not import a limitation into the

claims from the specification. Phillips, 415 F.3d at 1323. The Federal Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. Id. In other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. Id. (citing Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

A court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." Phillips, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id.

"The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correction construction." Renishaw PLC v. Marposs Societa' per Azionio, 158 F.3d 1243, 1250

(Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." Osram GmbH v. Int'l Trade Comm'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996)). It is with these legal principles in mind that the Court now turns to the construction of the disputed term among the asserted claims of the patents-in-suit.

III. ANALYSIS

The term "0.001%" appears in several claims in the patents-in-suit. AstraZeneca argues that "0.001%" should be construed by its plain meaning, "which is '0.001%, expressed using one significant digit.'" (Dkt. No. 292 at 5). Mylan contends that "0.001%" "means that precise number, with only minor variations" because AstraZeneca abandoned its proposed construction of "0.001%" during prosecution of the patents-in-suit (Dkt. No. 288 at 4).

A. The Claims

The Court begins its analysis by looking to the "actual words of the claim," Becton, Dickinson and Co. v. Tyco Healthcare Group, LP, 616 F.3d 1249, 1254 (Fed. Cir. 2010), as well as the context in which the disputed term appears. Phillips, 415 F.3d at 1314. Patent claims come in two general forms: independent and dependent. 35

U.S.C. § 112(c). Independent claims do not refer to any other claim of the patent and are read separately to determine their scope. Inamin, Ltd. v. Magnetar Tech. Corp., 623 F. Supp.2d 1055, 1065 (C.D. Cal. 2009). Dependent claims, in contrast, refer to at least one other claim, include all of the limitations of the claim to which they refer, and specify a further limitation on that claim. 35 U.S.C. § 112(d); see also Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1357 (Fed. Cir. 2007).

1. The '328 Claims

Independent claim 1 reads:

> 1. A pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, 1,1,1,2,3,3,3-heptafluoropropane (HFA277), PVP K25 (polyvinyl pyrrolidone with a nominal K-value of 25), and PEG-1000 (polyethylene glycol with an average molecular weight of 1,000), wherein the formoterol fumarate dihydrate is present at a concentration of 0.09 mg/ml, the budesonide is present at a concentration in the range of 1 mg/ml to 8 mg/ml, the PVP K25 is present at a concentration of 0.001% w/w, and the PEG-1000 is present at a concentration of 0.3% w/w.

'328 patent, col. 8. Independent claim 12 reads:

> 12. A pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP K25, and PEG-1000, wherein the formoterol fumarate dihydrate is present at a concentration of 0.09 mg/ml, the budesonide is present at a concentration of 1 mg/ml, the PVP K25 is present at a concentration of 0.001% w/w, and the PEG-1000 is present at a concentration of 0.3% w/w.

Id. Independent claim 13 reads:

> 13. A pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP K25, and PEG-1000, wherein the formoterol fumarate dihydrate is present at a concentration of 0.09 mg/ml, the budesonide is present at a concentration of 2 mg/ml, the PVP K25 is present at a concentration of 0.001% w/w, and the PEG-1000 is present at a concentration of 0.3% w/w.

Id. Independent claim 14 reads:

> 14. A pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP K25, and PEG-1000, wherein the formoterol fumarate dihydrate is present at a concentration of 0.09 mg/ml, the budesonide is present at a concentration of 4 mg/ml, the PVP K25 is present at a concentration of 0.001% w/w, and the PEG-1000 is present at a concentration of 0.3% w/w.

Id. at cols. 8, 9. Independent claim 15 reads:

> 15. A pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP K25, and PEG-1000, wherein the formoterol fumarate dihydrate is present at a concentration of 0.09 mg/ml, the budesonide is present at a concentration of 8 mg/ml, the PVP K25 is present at a concentration of 0.001% w/w, and the PEG-1000 is present at a concentration of 0.3% w/w.

Id. at cols. 9, 10.

2. The '239 Claims

Independent claim 1 reads:

> 1. A pressurized metered dose inhaler containing a suspension composition comprising formoterol fumarate dihydrate in the form of particles; budesonide in the form of particles; 1,1,1,2,3,3,3-heptafluoropropane (HFA227); polyvinyl pyrrolidone (PVP); and polyethylene glycol (PEG), wherein the budesonide is present in the composition at a concentration in the range of 1 mg/ml to 8 mg/ml, the PVP is present at a concentration in the range of 0.001% to 0.01% w/w, and the PEG is present at a concentration in the range of 0.05 to 0.5% w/w, and

> wherein an actuation of the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 40 to 320 µg budesonide.

'239 patent, cols. 8 and 9. Dependent claim 4 recites that the PVP is present in the composition at a concentration of 0.001% w/w. Id. at col. 9. Independent claim 10 reads:

> 10. A pressurized metered dose inhaler containing a suspension composition comprising formoterol fumarate dihydrate in the form of particles; budesonide in the form of particles; 1,1,1,2,3,3,3-heptafluoropropane (HFA227); PVP K25 (polyvinyl pyrrolidone with a nominal K-value of 25); and PEG-1000 (polyethylene glycol with an average molecular weight of 1,000), wherein the budesonide is present at a concentration in the range of 1 mg/ml to 8 mg/ml; the PVP K25 is present at a concentration of 0.001% w/w; and the PEG-1000 is present at a concentration of 0.3% w/w, and wherein an actuation of the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 40 to 320 µg budesonide.

Id. Independent claim 16 reads:

> 16. A method of administering an inhalable composition to a patient, the method comprising providing a pressurized metered dose inhaler containing a suspension composition comprising formoterol fumarate dihydrate in the form of particles, budesonide in the form of particles, HFA227, PVP K25, and PEG-1000, wherein the budesonide is present at a concentration in the range of 1 mg/ml to 8 mg/ml; the PVP K25 is present at a concentration of 0.001% w/w; and the PEG-1000 is present at a concentration of 0.3% w/w , and wherein an actuation of the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 40 to 320 µg budesonide; and causing the patient to inhale the composition from the inhaler.

Id. at cols. 9, 10. Independent claim 24 reads:

> 24. A method of administering an inhalable composition to a patient, the method comprising providing a pressurized

> metered dose inhaler containing a suspension composition comprising formoterol fumarate dihydrate in the form of particles; budesonide in the form of particles; HFA227; PVP; and PEG, wherein the budesonide is present in the composition at a concentration in the range of 1 mg/ml to 8 mg/ml, the PVP is present at a concentration in the range of 0.001% to 0.01% w/w, and the PEG is present at a concentration in the range of 0.05 to 0.5% w/w, and wherein an actuation of the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 40 to 320 µg budesonide; and causing the patient to inhale the composition from the inhaler.

Id. at col. 10.

3. The '137 Claims

Independent claim 1 reads:

> 1. A pharmaceutical suspension composition comprising formoterol fumarate dihydrate; budesonide; 1,1,1,2,3,3,3-heptafluoropropane (HFA227); polyvinyl pyrrolidone (PVP); and polyethylene glycol (PEG), wherein the budesonide is present in the composition at a concentration in the range of 1 mg/ml to 8 mg/ml, the PVP is present at a concentration in the range of 0.001% to 0.01% w/w, and the PEG is present at a concentration in the range of 0.05 to 0.5% w/w.

'137 patent, col.8. Dependent claim 4 recites that the PVP is present in the composition at a concentration of 0.001% w/w. Id.

Independent claim 9 reads:

> 9. A pharmaceutical suspension composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP K25, and PEG-1000, wherein the budesonide is present at a concentration in the range of 1 mg/ml to 8 mg/ml and the PVP K25 is present at a concentration of 0.001% w/w.

Id. Dependent claim 25 recites that the PVP is at a concentration of 0.001% w/w. Id. at col. 9.

4. The '247 Claim

The only claim at issue regarding the '247 patent is dependent claim 4. Dependent claim 4 recites that "the pharmaceutical composition according to **claim 1**[1] in which the PVP is present in an amount of 0.001% w/w." '247 patent, col. 8 (emphasis in original).

B. The Claim Language

The center of the parties' dispute lies with how many significant digits are necessary to express the term "0.001%". Both parties agree that a person of ordinary skill in the art would interpret the specification to convey that the "0.001%" term is subject to rounding according to the number of significant digits. Thus, as advanced by AstraZeneca, the "0.001%" term would include a range from "0.0005%" to "0.0014%", based on the rules of rounding. Under Mylan's proposed construction, this range would include "0.00095" to "0.00105%". See, e.g., Noven Pharm., Inc. v. Actavis Labs. UT, Inc., C.A. No. 15-249-LPS, 2016 WL 3625541, at *3, 5 (D. Del. July 5, 2016) (construing "15 mg/cm^2" as its "[p]lain and ordinary meaning, i.e., '15 mg/cm^2' means 15 plus or minus at least .5, yielding a claimed range of greater than or

[1] Independent claim 1 reads, "A stable pharmaceutical composition comprising formoterol, budesonide or an epimer thereof, 1,1,1-2,3,3,3-heptafluoropropane (HFA227), polyvinyl pyrrolidone (PVP) and polyethylene glycol (PEG)." '247 patent, col. 8.

equal to 14.5 mg/cm^2 and less than 15.5 mg/cm^2").

The plain language of all of the relevant claims in the patents-in-suit states the term at issue as "0.001%." Mylan's proposed definition, which attempts to add a significant digit such that the claim term would be read as "0.0010%," conflicts with the plain language of the claim.

The task of the Court is to "define[] the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998). Here, neither the claim language nor prosecution history of the patents in suit indicates that AstraZeneca intended to include "0.001% expressed with two significant digits" in its claims. The Court is thus reluctant to follow Mylan's suggestion and rely on the prosecution history—where AstraZeneca never expressed "0.001%" or any of the other concentrations of PVP with more than one significant digit—to adopt a construction that might define the disputed term with greater specificity than warranted by the claim language.

C. The Specification

The Court turns to the patent specification in the patents-in-suit for guidance. Phillips, 415 F.3d at 1317. The specification

states that "[s]tability is one of the most important factors which determines whether a compound or a mixture of compounds can be developed into a therapeutically useful pharmaceutical product." '328 patent, col. 1:21-24; '239 patent, col. 1:25-28; '137 patent, col. 1:26-30; '247 patent, col. 1:12-15. The specification also teaches that the PVP is "preferably" present "in an amount of 0.001% w/w." '328 patent, col. 1:46; '239 patent, col. 1:49; '137 patent, col. 1:48; '247 patent, col. 1:48. The "0.001% w/w" concentration of PVP "used in this formulation has been found to give consistently stable formulations over the required dose range, incorporating a wide range of concentrations of the active components, and at a much lower concentration than indicated in the prior art." '328 patent, col. 2:17-21; '239 patent, col. 2:22-26; '137 patent, col. 2:18-22; '247 patent, col. 2:11-15.

While the specification is often described as "'the single best guide to the meaning of a disputed term,'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582), "the scope of patent protection" is defined by "[t]he claims, not specification embodiments." Kara Technology Inc. v. Stamps.com, Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009). After a careful review of the specification, it is clear that AstraZeneca used "0.001%" consistently with a single significant digit.

D. The Prosecution History

Mylan's strongest argument relies on the prosecution history of the patents-in-suit. According to Mylan, its proposed construction is supported because, during the prosecution of the patents, AstraZeneca engaged in multiple rounds of patent argument and ultimately narrowed its original claim for PVP concentration to "0.001%." (Dkt. No. 288 at 6). Mylan argues that this adjustment establishes that AstraZeneca disclaimed all other concentrations of PVP, and that the patents-in-suit all claim a PVP concentration of precisely "0.001%". Id. In support of its argument, Mylan asserts that during prosecution AstraZeneca favorably distinguished its proposed invention from the prior art by demonstrating the criticality of 0.001% PVP to the stability of the pharmaceutical composition. Id. Mylan also points to AstraZeneca's limitation and argument that 0.001% PVP "suprising[ly]" provided the "best results" in terms of stability. Id.

AstraZeneca, however, contends that during prosecution it never disclaimed "0.001%" expressed with one significant digit (Dkt. No. 308 at 9). It insists there was no disavowal or disclaimer of the claim scope because expressing a preference for "0.001%" w/w PVP does not rise to the level of clear and unequivocal evidence that the claimed invention did not include

other embodiments of PVP, such as 0.0005%, that would be included in rounding "0.001%" to a single significant digit. Id. at 8. Importantly, AstraZeneca points out that it never expressed a PVP concentration in the invention with more than one significant digit during the prosecution history. Id. at 7.

In context, AstraZeneca's proposed construction is consistent with the claim language and specification of the patents-in-suit. See Phillips, 415 F.3d at 1317 ("Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes."). Undoubtedly, by adjusting its PVP preference, AstraZeneca was attempting to distinguish the prior art, which revealed stability in a range of 0.0025% w/w to 0.5% w/w PVP (Dkt. No. 288-3 at 26). But the evidence relied on by Mylan falls short of the "clear and unmistakable disavowal" needed to overcome "the heavy presumption that claim terms carry their full ordinary and customary meaning." Biogen Idec, Inc. v. GlaxoSmithKline LLC, 713 F.3d 1090, 1095 (Fed. Cir. 2013) (internal citations and quotation marks omitted). Therefore, because the ordinary and customary meaning of "0.001%" would be to read "0.001%" with one significant digit, the Court

declines to adopt Mylan's proposed construction based on the prosecution history of the patents-in-suit.

IV. CONCLUSION

The Court **ADOPTS** AstraZeneca's proposed construction and **CONSTRUES** the term "0.001%" consistent with its plain and ordinary meaning, that is, expressed with one significant digit.

It is so **ORDERED.**

The Clerk is directed to transmit copies of this Order to counsel of record.

DATED: August 12, 2020

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE